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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/382,242	08/24/1999	DAN E. ROBERTSON	DIVER1180-1	4972

20985 7590 07/29/2003

FISH & RICHARDSON, PC
4350 LA JOLLA VILLAGE DRIVE
SUITE 500
SAN DIEGO, CA 92122

EXAMINER	
PROUTY, REBECCA E	
ART UNIT	PAPER NUMBER
1652	27

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/382,242	Applicant(s) Robertson et al.
	Examiner Rebecca Prouty	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 13, 2003* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *21 and 26-53* is/are pending in the application.

4a) Of the above, claim(s) *51* is/are withdrawn from consideration.

5) ☒ Claim(s) *21 and 44-46* is/are allowed.

6) ☒ Claim(s) *26-43, 47-50, 52, and 53* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1-20 and 22-25 have been canceled. Claims 21, 26-33 and newly presented claims 34-53 are still at issue and are present for examination.

Applicants' arguments filed on 5-13-03, paper No. 26, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Newly submitted claim 51 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The invention of the previously examined claims and Claim 51 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the probes of the examined claims can be used for detecting a esterase gene.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

on the merits. Accordingly, claim 51 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 32-33, 40-42 and 47-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32 (as dependent on Claim 23), 40, and 47 (upon which Claims 33, 41, and 42 depend) are confusing as reciting additional limitations excluded from the claims from which they depend. Each of Claims 21 (upon which Claim 32 depends), 34 (upon which Claim 40 depends), 35 (upon which Claim 40 depends), and 44 (upon which Claim 47 depends) are limited to oligonucleotide probes **consisting** of a nucleic acid sequence. Therefore each of these claims explicitly excludes other additional components within the probe and thus the recitation of "further comprises a detectable label" is confusing. It is suggested that these claims be amended in the format "An oligonucleotide probe consisting of the oligonucleotide probe of Claim 21 (or 34, 35 or 44) and a detectable label.".

Claim 48 (upon which Claims 49 and 50 depend) is indefinite in the recitation of "specifically binds to a nucleic acid having

90% identity to SEQ ID NO:23" as it is unclear how a nucleic acid can specifically bind to more than one nucleic acid sequence as specifically bind in the art means binds to a particular nucleic acid sequence but not to other different sequences.

Claims 26-43, 48-50, 52 and 53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of oligonucleotide probes which comprise a sequence which specifically hybridizes to SEQ ID NO:23, its complement or to a nucleic acid having 95% identity thereto.

The specification does not contain any disclosure of the structure and function of all oligonucleotide probes which comprise/consist of a sequence which hybridizes to SEQ ID NO:23, its complement or to a nucleic acid having 90% or 95% identity thereto. The genus of probes that comprise a sequence which specifically hybridizes to SEQ ID NO:23, its complement or to a nucleic acid having 95% identity thereto is a large variable genus with the potentiality of encoding many different proteins. Therefore, many structurally and functionally unrelated DNAs are encompassed within the scope of these claims, including partial

DNA sequences. The specification discloses only SEQ ID NO:23 which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Applicants argue that the claimed probes are described by both structural and functional features analogously to example 14 of the written description guidelines. This is not persuasive because the claims do not in fact recite any functional limitation analogous to that recited in example 14 of the guidelines. Applicants argue that the claims are limited to the function of "binding to, amplifying and/or detecting an esterase-encoding nucleic acid". However, the ability to bind to a particular sequence is not a function at all but merely defines the possible structure(s) of the compound and the presence of the ability to bind does not correlate to an ability to detect an esterase encoding sequence as the presence of structural

similarity to a sequence **does not** provide an assurance of functional identity. The claimed oligonucleotides will bind to both esterase encoding sequences (such as SEQ ID NO:23) and non-esterase encoding sequences (such as variants of SEQ ID NO:23 with single substitutions which encode catalytically inactive proteins) under the recited hybridization conditions. As such the claimed genus of nucleic acids unlike that of example 14 of the guidelines is diverse in functional features. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 26-43, 48-50, and 52-53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a probe consisting of a fragment of SEQ ID NO:23 which will hybridize to SEQ ID NO:23 under stringent conditions and optionally a detectable label, does not reasonably provide enablement for any probe which hybridizes to any nucleic acid having 90% or 95% identity to SEQ ID NO:23 under the recited conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope

with these claims. The rejection is explained in the previous Office Action.

Applicants argue that the amendment of the claims to recite the specific hybridization conditions addresses the problems addressed previously that the skilled artisan would require undue experimentation to design probes which would specifically detect any particular sequence. However, it is noted that the amendments do not in fact address the issue of undue experimentation with regard to how to use the full scope of the claimed oligonucleotides. Applicants claims include, at the very least, all oligonucleotides consisting of a sequence which will hybridize to SEQ ID NO:23 under the recited conditions, and many of the claims are substantially broader in scope. Applicants asserted utility for these sequence is for the detection of esterase encoding sequences. Detection requires selective hybridization to the target. However, the recited hybridization conditions are very low stringency such that the scope of the claimed genus of probes is enormous. Most of the probes encompassed will hybridize under the recited conditions to an enormous number of possible sequences the vast majority of which will not encode an esterase protein. While the skilled artisan would understand that fragments of SEQ ID NO:23 itself would selectively hybridize to SEQ ID NO:23 under more stringent

conditions, variant sequences (as also encompassed by the claims) would not and in fact would hybridize to some other sequence if selective conditions were utilized. As such the skilled artisan would require undue experimentation to use most of the oligonucleotides claimed as asserted in the specification.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26-30, 48-49, and 52-53 are rejected under 35 U.S.C. 102(a or b) as being anticipated by GenBank Accession No. X86487 or Kim et al.

GenBank Accession No. X86487 and Kim et al. each teach the isolation of a gene having a nucleotide sequence comprising at least 15 nucleotides of the nucleotide sequence of SEQ ID NO:23, and vectors and host cells containing these genes. Bases 21-39 of the gene of GenBank Accession No. X86487 are identical to bases 360-378 of SEQ ID NO:23 and bases 5051-5069 of the gene of Kim et al. are identical to bases 505-523 of SEQ ID NO:23. As bases 21-39 of the sequence of GenBank Accession No. X86487 are

100% identical to bases 360-378 of SEQ ID NO:23 and bases 5051-5069 of the gene of Kim et al. are 100% identical to bases 505-523 of SEQ ID NO:23, each of these fragments would unquestionably specifically hybridize to SEQ ID NO:23 and the nucleic acids of GenBank Accession No. X86487 and Kim et al. each clearly comprise these fragments.

Claims 21, and 44-46 are allowed. These claims are restricted oligonucleotides consisting of at least 15-50 contiguous nucleotides of SEQ ID NO:23. While the prior art teaches polynucleotides comprising at least 15 consecutive bases of SEQ ID NO:23 there is no suggestion in the prior art to select these specific portions of these larger polynucleotides for use as a probe.

Claim 47 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rebecca Prouty
Primary Examiner
Art Unit 1652